UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC
SHERR-UNA BOOKER, an individual, Plaintiff, v. C.R. BARD, INC., a New Jersey corporation and BARD PERIPHERAL VASCULAR, an Arizona corporation, Defendants.	**EXHIBIT INDEX** **PLAINTIFF, SHERR-UNA BOOKER'S SUPPLEMENT TO THE "PLAINTIFFS' OMNIBUS SEPARATE STATEMENT OF FACTS IN SUPPORT OF THEIR RESPONSE TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT IN THE BELLWETHER CASES"**

Exhibit B-A Plaintiff's Medical Records
(Redacted and Filed Under Seal)

Exhibit B-B Marcus D'Ayala M.D. Deposition Excerpts 3-21-17
(Redacted and Filed Under Seal)

Exhibit B-C Brandon Kang MD Deposition Excerpts 6-15-17
(Redacted and Filed Under Seal)

Exhibit B-D Harvey MD Deposition Excerpts 6-20-17
(Redacted and Filed Under Seal)

Exhibit B-E Sherr-Una Booker Deposition Excerpts 2-20-17
(Redacted and Filed Under Seal)

Exhibit B-F Robert Ferrara Deposition Excerpts 4-7-17

Exhibit B-G BPVE-01-00719569 (Filed Under Seal)

Exhibit B-H Natalie Wong Deposition Excerpts 10-18-16

Exhibit B-I BPVEFILTER-45-00019568 (Filed Under Seal)

Exhibit B-J BPV-17-01-00108473 (Filed Under Seal)

Exhibit B-K K102511-Meridian 8-24-11

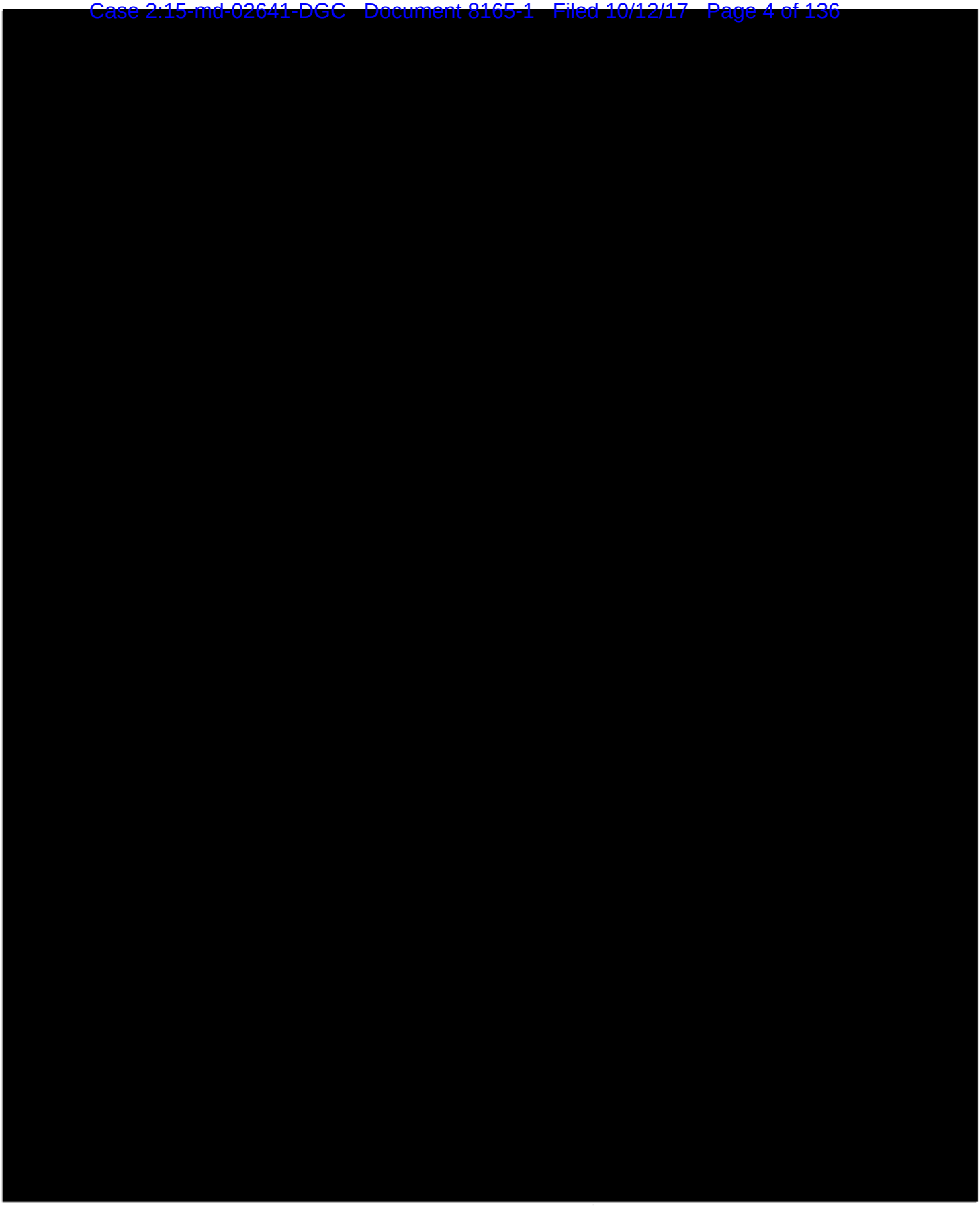
Exhibit B-L BPVEFILTER-45-00012404 (Filed Under Seal)

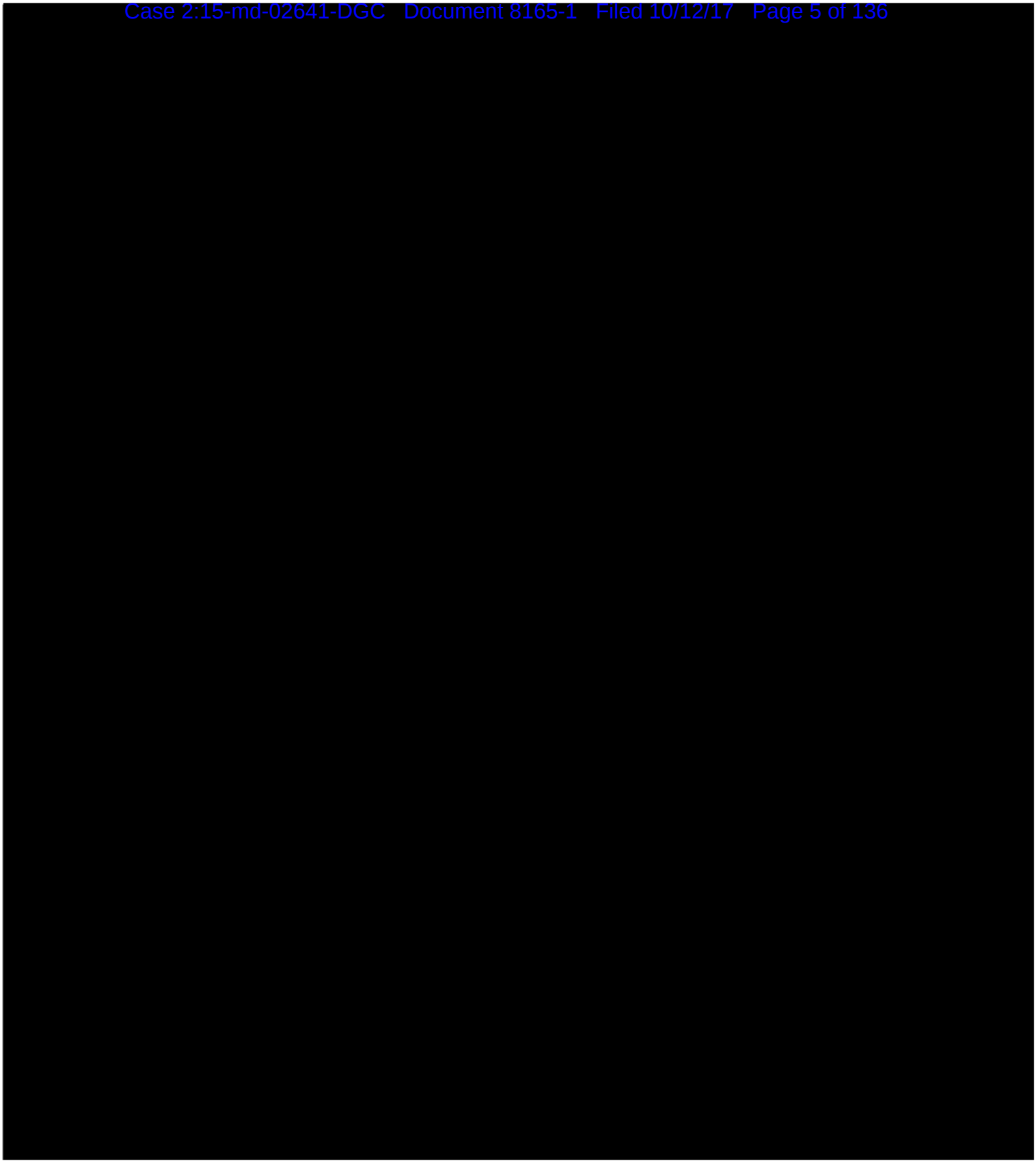
Exhibit B-M BPV-17-01-00148749 (Filed Under Seal)

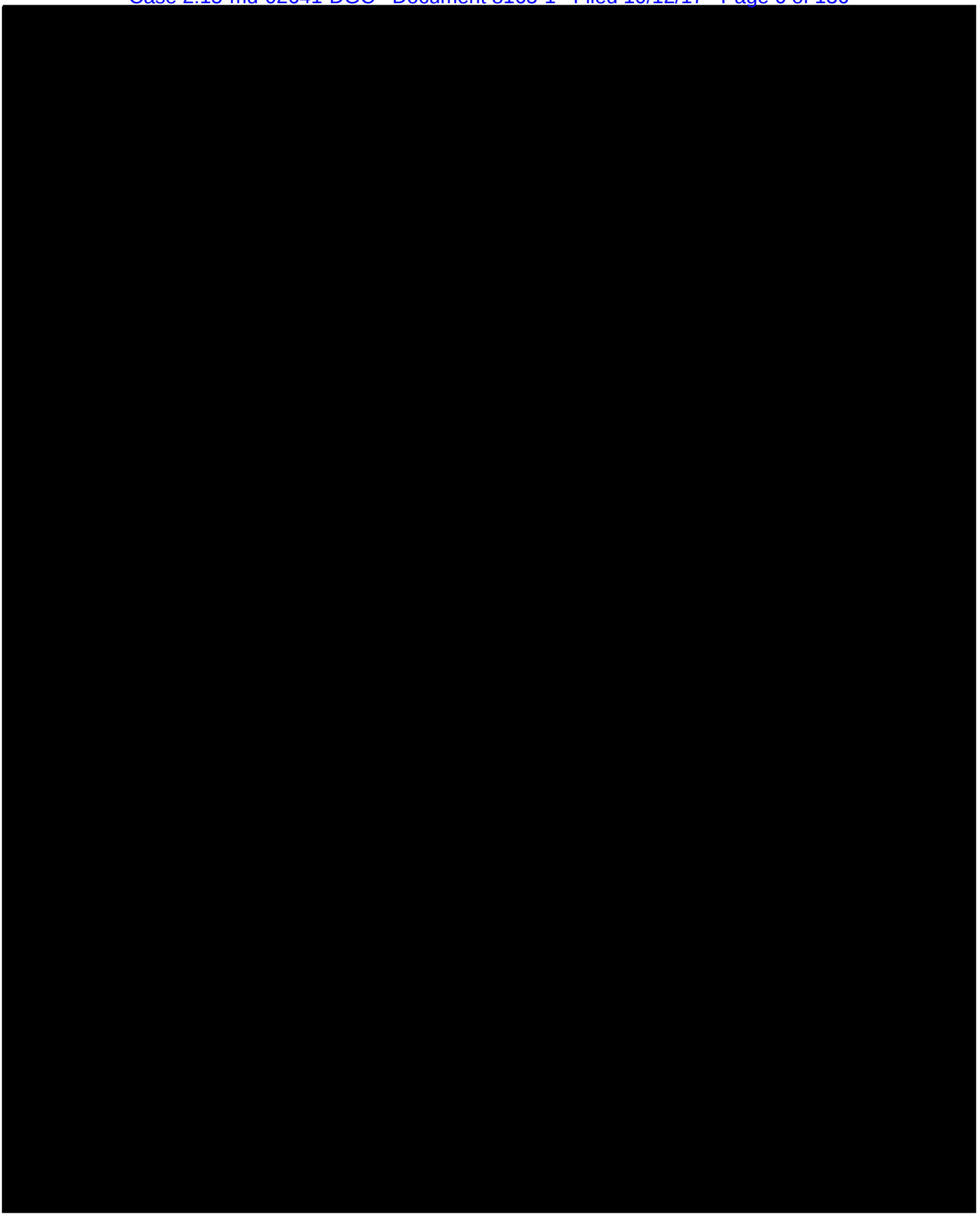
Exhibit B-N Mark W. Moritz M.D. Deposition Excerpts

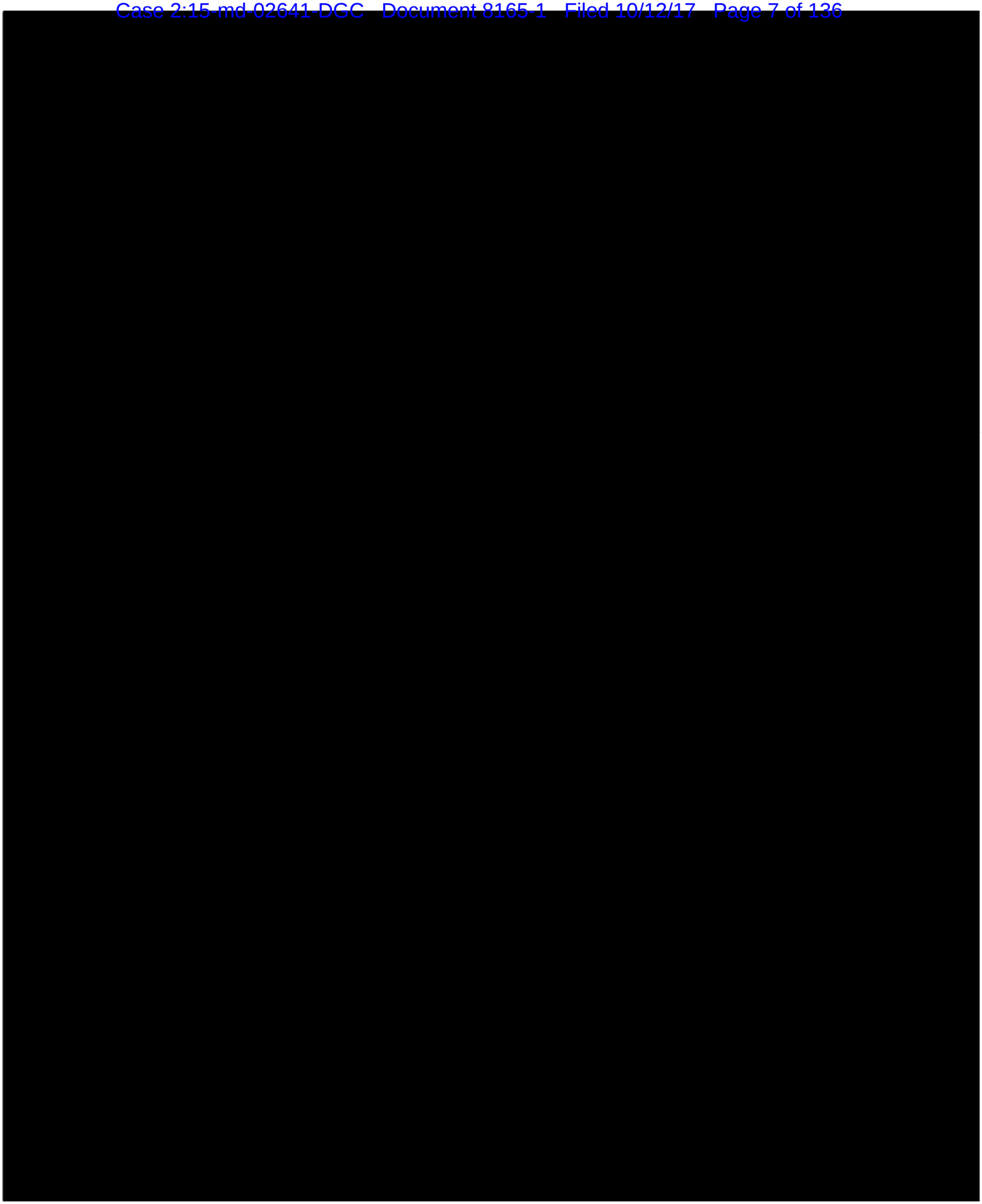
Exhibit B-A

(Redacted and Filed Under Seal)



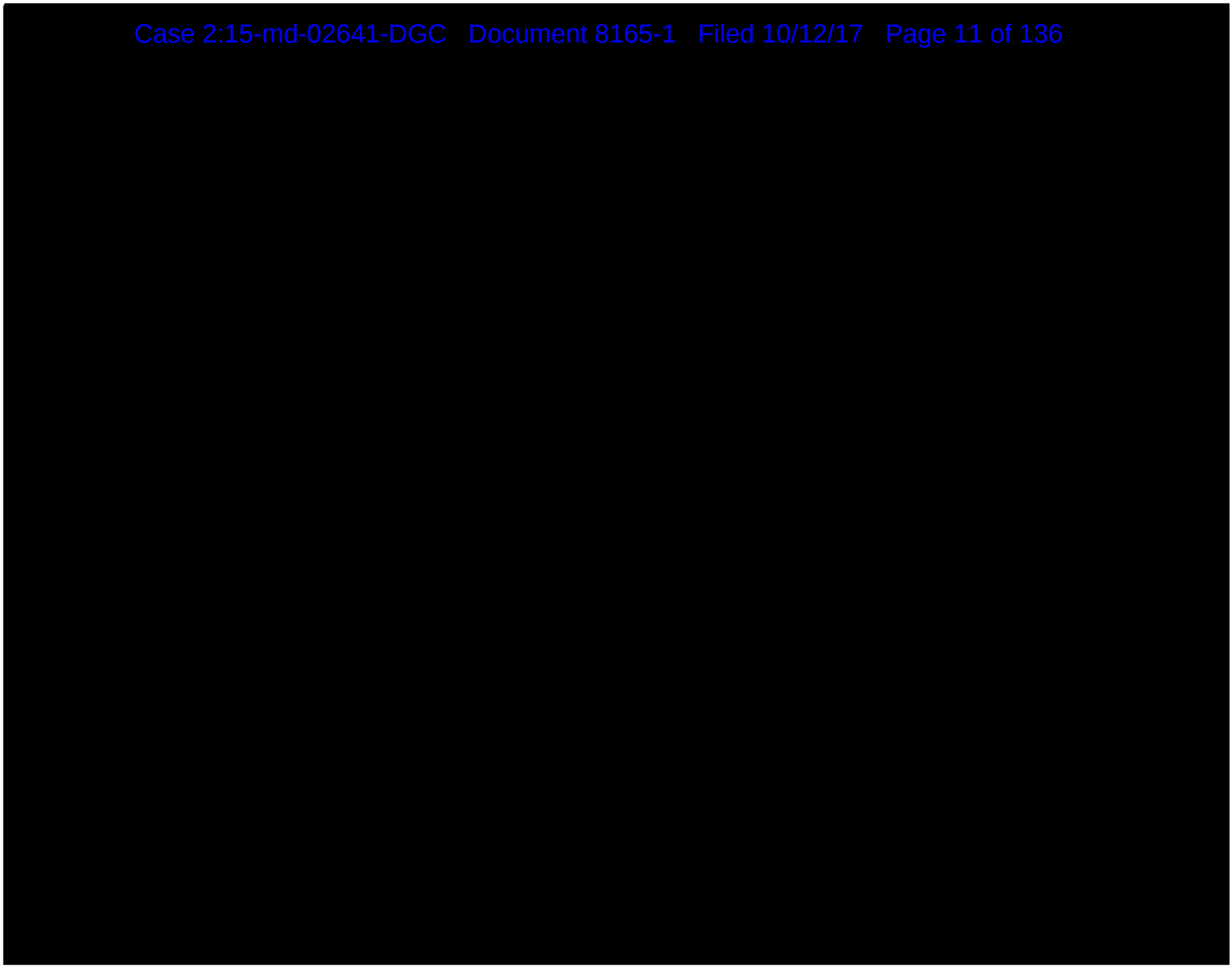




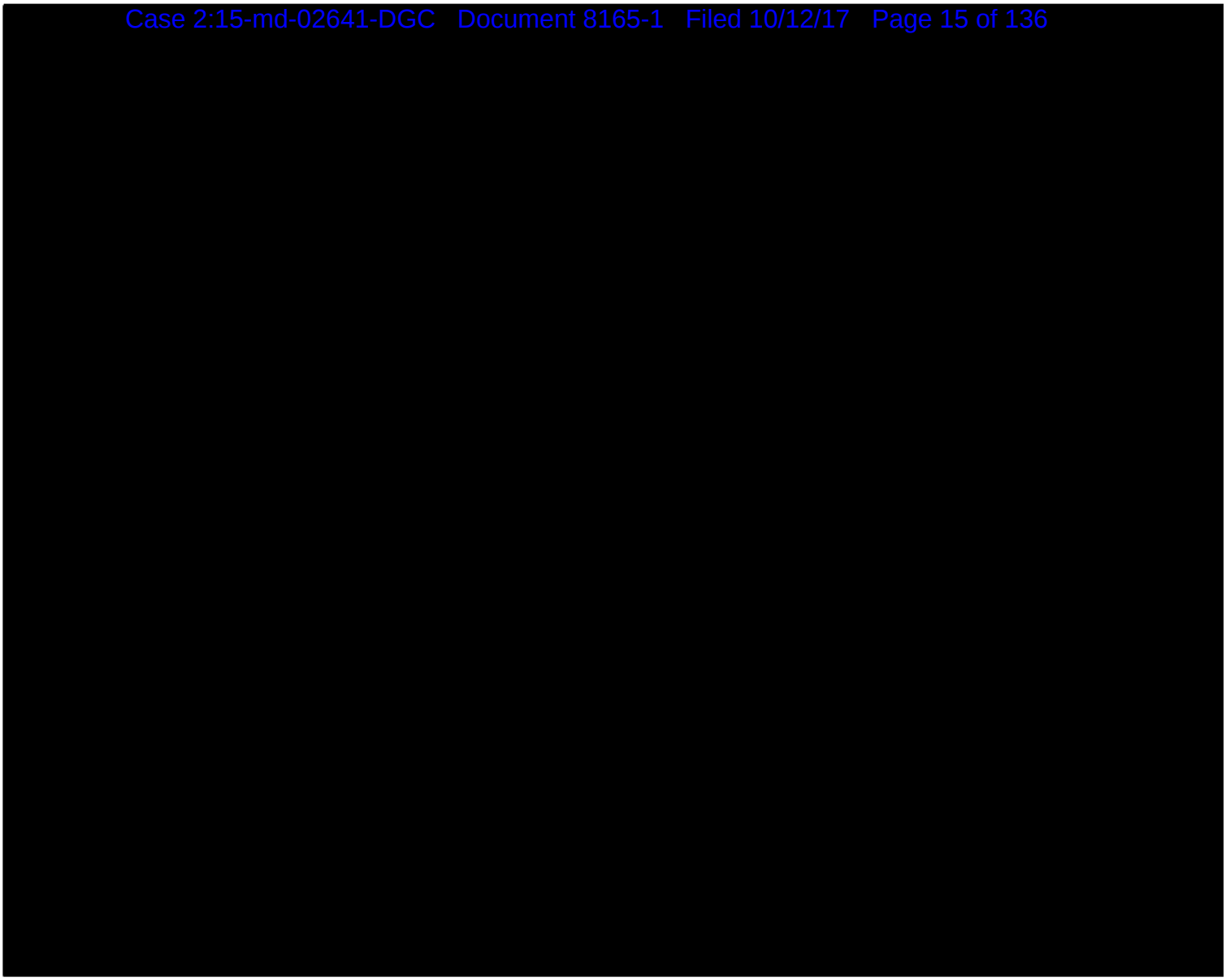


[redacted]

[redacted]



[redacted]



[redacted]

[redacted]

[redacted]

Exhibit B-B

(Redacted and Filed Under Seal)

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

- - -

IN RE BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION : NO. MD-15-02641-PHX-DGC

- - -

MARCH 21, 2017

- - -

DO NOT DISCLOSE - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

Videotape deposition of MARCUS D'AYALA, M.D., taken pursuant to notice, was held at the law offices of Aaronson Rappaport Feinstein & Deutsch, LLP, 600 Third Avenue, New York, New York 10016, beginning at 12:45 p.m., on the above date, before Amanda Dee Maslynsky-Miller, a Certified Realtime Reporter and Notary Public in and for the State of New York.

- - -

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deps@golkow.com

A. It is.

Q. All right. The other 80 percent of the time, you are a clinician; that is, you spend time treating patients?

A. Correct.

Q. All right.

A. With a small amount of that time dedicated to administration of our division.

[redacted]

A. I do not.

Q. Have you had a chance to look at the records, your records, [redacted]

A. I have.

Q. Other than the review of the medical record [redacted] did you look at any other medical records?

A. I did.

But for the sake of clarity, I must

will not treat that patient, in other words, that patient is being treated by someone else?

A. Yes.

Q. All right. And if there's a decision to remove a filter, that decision is often someone else's, whether it's a primary care physician, whether it's the orthopedic surgeon, whether it's the internist that's treating that patient, that decision oftentimes isn't even yours?

MS. HELM: Object to the form.

BY MR. MATTHEWS:

Q. Is that true? Is that basically true?

MS. HELM: Same objection.

THE WITNESS: I'm not entirely sure that I agree with that. I think we play an important role in retrieving these filters, or at least we try to.

So the whole issue of filter retrieval is one that has been an evolution over the years. And today it's part of our practice to advise these patients to return for follow-up to have filters retrieved, if it's possible to do so and do so safely.

So a number of requirements must be

met for us to retrieve these filters.

BY MR. MATTHEWS:

Q. I'm going to back up, if I could, because now we're talking about 2017 --

A. Correct.

Q. -- and 2007 is the time frame. So I'm going to ask a different question.

A. Okay.

Q. Back in 2007 when you were implanting in particular the G2, the G2 had only been cleared for permanent implantation; is that correct?

A. Correct.

Q. So you were implanting this filter as a permanent filter in 2007, correct?

A. Correct.

Q. At that time in 2007, [redacted] was intended as a permanent filter, correct?

MS. HELM: Object to the form.

THE WITNESS: Correct.

BY MR. MATTHEWS:

Q. All right. Well, let's talk about, then, a different subject, and that is your history with the use of filters.

Can you tell the jury when you first

timelines as to when these things were done.

Q. Did you ever use the Bard Recovery filter?

A. I believe I did.

Q. All right. So you used the Bard Recovery, the Bard G2, the Cordus TRAPEASE. And you said the Cook filters.

Do you recall which Cook filters you used?

A. We use the Günther Tulip and right now it's a variation of it called the Cook Celect, C, as in Charles, E-L-E-C-T.

Q. You said you moved away from the Bard filter because of problems associated with it, correct?

A. Yes.

MS. HELM: Object to the form.

BY MR. MATTHEWS:

Q. What were the problems associated with the Bard that -- the reason that you moved away from it?

A. There is a database known as the MAUDE database and it was becoming clear that there were numerous reports in the literature of filter fragmentation and filter migration with these

filters.

Q. Do you recall the time frame when you moved away from Bard filters?

A. I do not.

Q. Clearly it was after 2007, because you were still implanting the G2 in 2007, correct?

A. Correct.

Q. Were you called upon by a sales rep or somebody that's known as a detailer from Bard that came to your hospital to talk to you --

A. Yes.

Q. -- about their filters?

Do you recall that sales rep?

A. We had a number throughout the years from different corporations, so if you could be a little bit more specific.

Q. Well, I guess I'm referring to a sales rep by the name of Ferrara.

Do you recall a sales rep by the name of Ferrara?

A. Robert Ferrara?

Q. Ferrara, I'm sorry.

A. I do.

Q. Was he in your offices from time to time to talk about the Recovery and the G2?

A. Uh-huh.

Q. Yes?

A. Yes.

Q. I'm sorry. You've got to answer aloud for her.

A. Yes.

Q. Were you ever told by Mr. -- is it Ferrara?

A. Uh-huh.

Q. -- Mr. Ferrara that Bard had a crisis management plan, as early as 2004, to deal with the high rates of AEs, that being, adverse events, perforation, fracture and migration?

MS. HELM: Object to the form.

THE WITNESS: No.

BY MR. MATTHEWS:

Q. Were you ever told that Bard conducted an investigation in 2004 into the high number or large number of adverse events of the Recovery done by an independent investigator?

MS. HELM: Object to the form.

THE WITNESS: No.

BY MR. MATTHEWS:

Q. Were you ever sent a letter by the company that talked to you or -- I'm sorry, that

informed you about the results of this investigation, this independent investigation by Bard?

MS. HELM: Object to the form.

THE WITNESS: No.

BY MR. MATTHEWS:

Q. Were you ever told, either by letter or by Mr. Ferrara, that there was a 530 percent higher fracture rate than other filters on the market with the Bard Recovery?

MS. HELM: Object to the form.

THE WITNESS: No.

BY MR. MATTHEWS:

Q. Were you ever told that there was a 1,200 percent higher risk of death from the Recovery fracture and embolization to the heart than other filters on the market?

MS. HELM: Object to the form.

THE WITNESS: No.

BY MR. MATTHEWS:

Q. In 2004 and 2005, [redacted], would that have been important information for you to know? Assuming that that was information that was known to Bard, is that something that you would want

to have known?

A. Yes.

MS. HELM: Object to the form.

THE WITNESS: Can I interrupt for one second? I just wanted to clarify one other point.

Previously you asked me how many publications I had regarding filters. And there's actually a third publication that I had forgotten, and I see it here in my C.V. It's one in which a filter migrated to the heart. And with your question before, I remember you asking me about filters migrating to the heart.

BY MR. MATTHEWS:

Q. That was a case study, correct?

A. That was a case report, that's correct.

Q. Yes, case report. I did read that. Thank you.

MS. HELM: Do you mind telling us which number that is?

THE WITNESS: That would be 28 to 32 under publications.

BY MR. MATTHEWS:

Q. Let me show you what's been marked as Exhibit Number 2.

MS. HELM: Do you have a copy for me?

MR. MATTHEWS: This is a health hazard evaluation dated December 17th, 2004.

- - -

(Whereupon, Exhibit-2, BPVE-01-01019821-825, Health Hazard Evaluation, Dated 12/17/04, was marked for identification.)

- - -

THE WITNESS: Thank you.

BY MR. MATTHEWS:

Q. Let me show you, if you could turn. Just so we're clear on the record, this is a health hazard evaluation from David Ciavarella, MD, who I believe was the vice president of clinical trials -- clinical affairs, dated December 17th, 2004, to Doug Uelmen, BPV QA. And this is Recovery Filter Consultants Report, and I would turn your attention to the second page --

A. Okay.

Q. -- under Number 2. It says that, The consultant's analysis of the reports of Bard -- to Bard of adverse events associated with the Recovery, along with competitors' information available via the MAUDE and IMS databases, showed the following: Reports of death, filter migration, IVC perforation

and filter fracture associated with the Recovery filter were seen in the MAUDE database at reporting rates that were 4.6, 4.4, 4.1 and 5.3 higher, respectively, than reporting rates for all other filters.

Doctor, this is dated December 17th, 2004. Would this have been important information for you to know, that is, a doctor who is implanting Recovery filters, that those filters had a greater risk of fracture that's four and five times higher than the competitor filters?

MS. HELM: Object to the form.

THE WITNESS: Yes.

BY MR. MATTHEWS:

Q. Is that the type of information that would influence your prescribing habits, whether you would use that filter, a Bard filter, or another filter?

MS. HELM: Object to the form.

THE WITNESS: Yes.

BY MR. MATTHEWS:

Q. Let me show you what's been marked as Exhibit-3, which is the Recovery filter migration, Remedial Action Plan, dated January 4, 2005.

- - -

(Whereupon, Exhibit-3, BPVE-01-01019773-784, Recovery Filter Migration, Dated 1/4/05, was marked for identification.)

- - -

BY MR. MATTHEWS:

Q. [redacted]

[redacted]

And I would turn your attention to the first, second, third, fourth, fifth page. It says, actually, 1 of 7 on the fifth page of that document.

A. I'm sorry, could you --

Q. At the bottom under Roman III.

It says, Identification of the problem: As part of the ongoing evaluation of RNF, Recovery Nitinol filter, Bard requested an independent study of the risks and benefits of the RNF, with an emphasis on its use in bariatric surgery and trauma patients. A consultant was retained for this purpose and reported the following: The MAUDE database maintained by the FDA was reviewed. The reporting rates between the RNF and aggregates of the other commercialized vena cava filters were compared.

A, in the MAUDE dataset, the RNF

demonstrated a consistent statistically significant and potentially clinically important higher rate of reporting of adverse events in several analyzed categories.

B, given the pattern of reported events, a higher rate of death reports seem related to filter movement and filter embolization.

You referenced the MAUDE database earlier in questions, Doctor. Is that information important to you as a doctor that is implanting the Recovery filter?

MS. HELM: Object to the form.

MR. LERNER: Which information?

MR. MATTHEWS: That is A and B that I just read.

MS. HELM: Object to the form.

MR. LERNER: But you questioned him, you said you referenced the MAUDE database before. Your question then becomes confusing. I'm asking you to clarify it.

MR. MATTHEWS: All right. I'll strike it and ask another question.

BY MR. MATTHEWS:

Q. In looking at A and B, Doctor, is that the type of information that's important to you

to know prior to implanting a Recovery filter?

A. Yes.

MS. HELM: Object to the form.

BY MR. MATTHEWS:

Q. Do you know what the term "statistically significant" means?

A. I do.

Q. And that's an important epidemiological statement, correct?

MS. HELM: Object to the form.

THE WITNESS: Statistical statement, yes.

BY MR. MATTHEWS:

Q. Doctor, at the Methodist Hospital in 2007, did you have more than one filter at your disposal? That is, you talked about, I think you told me, you had the TRAPEASE, you had the Tulip, and you had the Recovery, and you had the select.

Were all of those available back in 2007, do you recall?

A. No.

Q. Do you know which were available?

A. The G2.

Q. That was the only one available in the hospital?

MS. HELM: Object to the form.

MR. LERNER: That particular filter?

MR. MATTHEWS: That particular filter.

THE WITNESS: The PREPIC 1 trial is a great study, and it's a very interesting study. But there are problems in this study, as there are problems with every study. And the fundamental problem that you have with this trial is that it randomized patients who were candidates for caval interruption or not; in other words, all patients were treated with blood thinners. It doesn't really address the question of what to do with those patients that cannot be treated with blood thinners.

[redacted]

With regards to the Bard filter,

would I have used a different device if I knew at the time that the Bard filter was not ideal or as good as some of the other implants? The answer would have to be yes.

BY MR. MATTHEWS:

Q. You would have used --

A. I would have used a different filter if there was a different filter that I knew of that was better, in terms of its safety profile.

Q. In terms of the documents that you have, I think they are Exhibit-2 and 3, the health hazard report and then the investigation conducted by Bard that showed a fivefold increased risk for fracture and embolization of that fracture, and you told us that would be the type of information you would want to know in your benefit/risk analysis, knowing that --

A. Yes.

Q. -- and seeing that today, would that have been enough to use another filter?

MS. HELM: Object to the form.

THE WITNESS: Difficult to say with certainty. It would depend upon what other filters we had at the time and what their problems would have been. But it would have been a very important

piece of information, as far as making decisions regarding this or any other patient, yes.

BY MR. MATTHEWS:

Q. And it would have influenced your prescribing habit?

MS. HELM: Object to the form.

THE WITNESS: Yes.

BY MR. MATTHEWS:

Q. Let me show you a study, I'm going to mark this as D'Ayala Exhibit Number 7. And this is entitled, The Prevalence of Fracture -- I'm sorry, let me hand that to you.

A. Sure.

Q. The Prevalence of Fracture and Fragment Embolization of Bard Retrievable Vena Cava Filters and Clinical Implications Including Cardiac Perforation and Tamponade.

- - -

(Whereupon, Exhibit-7, AMA, Prevalence of Fracture and Fragment Embolization of Bard Retrievable Vena Cava Filters and Clinical Implications Including Cardiac Perforation and Tamponade, was marked for identification.)

- - -

BY MR. MATTHEWS:

if you extrapolate indwelling time with the G2 filter, that making it a 25 percent filter fracture rate for the G2.

Do you understand that premise within the paper?

A. I think I understand the premise. I'm not so sure that I understand the science behind it.

Q. Well, let me ask you this question, then, Doctor: If you knew back in 2007 [redacted] there was even a 12 percent probability of fracture with that filter, would you have used a G2?

MS. HELM: Object to the form.

THE WITNESS: Unlikely.

BY MR. MATTHEWS:

Q. If there was a 25 percent risk of filter fracture, can we safely say you would not have used that filter?

A. Most likely. But you have to understand that you have to have a way of treating these difficult patients. So some filter has to be used. And it becomes a matter of deciding which filter is best, so to speak. And sometimes that's not entirely clear.

Are you there?

A. Uh-huh.

MR. MATTHEWS: Is everybody there?

BY MR. MATTHEWS:

Q. There's some handwritten notes here. Are these yours?

A. No.

Q. Is the bottom right-hand corner yours?

A. No.

Q. If we could move to the next one, which is MDR69.

A. Uh-huh.

Q. Any of those notes yours?

A. Yes, that's all written by me.

Q. Okay. It says, that I can read, [redacted]

A. Uh-huh.

Q. Can you read that?

A. [redacted] PE. [redacted]

[redacted]

Q. All right. And the next entry that may or may not be yours, Page 71.

A. No, that's -- that's mine.

Q. It is? Okay.

A. Unmistakable.

Q. All right. I think that says,

[redacted]

A. I'd be happy to translate into English --

Q. Yes, please.

A. -- if you'd like.

[redacted]

Q. I'm sorry. On top of that, what does that say? Does that say duplex?

A. I'm sorry, you're in the second box?

[redacted]

Q. I apologize. Can we start over on the first box?

A. The top box?

Q. Yes, I messed up.

A. Sure. [redacted]

[redacted]

Q. [redacted]

[redacted]

A. Correct.

Q. And that's done -- how is that done?

A. Using ultrasound.

Q. All right.

A. So the way duplex

Q. Externally

A. Correct, it's a non-invasive procedure.

Q. Is that the gold standard for determining DVT, would you say?

A. It depends upon the clinical scenario. But, yes, it's the imaging modality of choice for lower extremity DVT.

Q. [redacted]

[redacted]

[redacted]

[redacted]

MS. HELM: For the record, can we identify it by the Bates number, please?

MR. MATTHEWS: Yeah, Bates stamped 108 and 109. It's a two-page document.

MS. HELM: Thank you.

BY MR. MATTHEWS:

Q. I think this is all legible.

A. Indeed.

Q. [redacted]

[redacted]

[redacted]

That actual -- is that actually

[redacted]

MR. MATTHEWS: Object to the form.

THE WITNESS: [redacted]

BY MS. HELM:

Q. [redacted]

[redacted]

MR. MATTHEWS: Object to the form.

THE WITNESS: [redacted]

BY MS. HELM:

Q. [redacted]

[redacted]

Q. [redacted] in 2007, you were aware, as you've stated, that filter fracture was a risk associated with a G2 and all filters; is that right?

A. Yes.

Q. [redacted]

their decision-making process.

Q. [redacted]

[redacted]

Q. Okay. Based on your review of the

Exhibit B-C

(Redacted and Filed Under Seal)

UNITED STATES DISTRICT COURT
DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	§	No. MD-15-02641-PHX-DGC

- - -

Thursday, June 15, 2017

- - -

** DO NOT DISCLOSE **

** SUBJECT TO FURTHER CONFIDENTIALITY REVIEW **

- - -

Videotaped deposition of BRANDON KANG, M.D., held at Mahaffey, Pickens & Tucker, 1550 North Brown Road, Suite 125, Lawrenceville, Georgia, commencing at 10:09 a.m., on the above date, before Susan D. Wasilewski, Registered Professional Reporter, Certified Realtime Reporter, Certified Realtime Captioner, Certified Manager of Reporting Services, Florida Professional Reporter, Certified Court Reporter (NJ), and Realtime Systems Administrator

- - -

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[redacted]

Q. Yes, sir. All right.

(Kang Exhibit 4 was marked for identification.)

BY MR. ROLL:

Q. And we have [redacted] that I will mark as Exhibit 4.

MS. LOURIE: Your microphone.

Q. All right. My microphone fell off. Sorry, Doctor.

All right. So Exhibit 4, could you take a look at that and identify that for us?

A. [redacted]

Q. All right. [redacted]

A. Correct.

Q. If you could just describe for me [redacted]

A. Sure.

Q. [redacted]--

A. [redacted]

MS. HELM: Excuse me. Object to the form.

Q. Could you describe for me what [redacted]

A. [redacted]

[redacted]

MS. HELM: Object to the responsiveness and move to strike.

Q. Would you state whether or not [redacted]

[redacted]

A. [redacted]

Q. I'm sorry.

MS. HELM: You're going to have to let me -- I'm sorry.

THE WITNESS: I'm sorry.

[redacted]

MS. HELM: Object to the responsiveness and move to strike.

Q. With regard to [redacted]

[redacted]

A. [redacted]

Q. Okay. [redacted]

[redacted]

A. [redacted]

MS. HELM: Object to the form.

A. [redacted]

Q. Okay. Had you formed an opinion, [redacted]

[redacted]

MS. HELM: Object to the form.

A. [redacted]

[redacted]

[redacted]

MS. HELM: Object to the responsiveness.

Q. All right. And did you form an opinion specifically [redacted]

MS. HELM: Object to the form.

A. [redacted]

MS. HELM: Object to the responsiveness.

Q. And is this [redacted]

[redacted]

MS. HELM: Object to the form.

A. [redacted]

Q. Would you state whether or not you had formed an opinion that it was prudent and in the best interest of the patient [redacted]

MS. HELM: Object to the form.

A. [redacted]

Q. Okay. Now, [redacted]

A. [redacted]

[redacted]

MS. HELM: Objection to the responsiveness and move to strike.

Q. Okay. Did you have an occasion [redacted] -- let me start over.

Did you have an occasion [redacted]

[redacted]

MS. HELM: Object to the form.

Q. Simply put: [redacted]

A. [redacted]

Q. [redacted]

A. [redacted]

(Kang Exhibit 5 was marked for

identification.)

BY MR. ROLL:

Q. I'm going to mark as Exhibit 5 the [redacted]

[redacted]

[redacted]

[redacted]

A. [redacted]

Q. All right. And I see at the bottom of this, on the second page, [redacted]

[redacted]

MS. HELM: Object -- object to the form.

A. [redacted]

Q. All right. Were you aware [redacted]

[redacted]

[redacted]

[redacted]

A. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Q. [redacted]

A. [redacted]

[redacted]

Q. All right. [redacted]

[redacted]

[redacted]

A. [redacted]

Q. [redacted]

[redacted]

MS. HELM: Object to the form.

A. [redacted]

[redacted]

Q. Right. [redacted]

[redacted]

MS. HELM: Object to the form.

Q. Well, let's just summarize. [redacted]

[redacted]

[redacted]

A. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Q. Okay. [redacted]

[redacted]

[redacted]

A. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Q. Okay. Well, let me stop you there, if I may.

A. Okay.

Q. [redacted]

[redacted]

A. [redacted]

Q. Which, of course, [redacted]

A. [redacted]

Q. [redacted]

[redacted]

[redacted]

A. [redacted]

Q. [redacted]

[redacted]

A. [redacted]

Q. And was this a -- [redacted]

[redacted]

A. [redacted]

Q. [redacted]

[redacted]

MS. HELM: Object to the form.

Q. You can answer the question.

A. What was the question exactly?

Q. [redacted]

[redacted]

MS. HELM: Object to the form.

Q. You can answer the question.

A. [redacted]

[redacted]

Q. [redacted]

[redacted]

A. [redacted]

[redacted]

[redacted]

[redacted]

Q. [redacted]

A. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Q. All right. [redacted]

[redacted]

A. [redacted]

Q. --[redacted]

[redacted]

A. [redacted]

[redacted]

Q. All right. And describe for me [redacted]

[redacted]

A. Sure. [redacted]

[redacted]

Q. Okay. [redacted]

[redacted]

A. [redacted]

Q. [redacted]

[redacted]

A. [redacted]

Q. Okay. [redacted]

A. [redacted]

Q. Okay. [redacted]

[redacted]

A. Well, [redacted]

[redacted]

[redacted]

Q. Okay.

A. So what you would describe [redacted]

[redacted]

Q. [redacted]

[redacted]

A. [redacted]

Q. And did its -- [redacted]

[redacted]

in your opinion?

MS. HELM: Object to the form.

A. [redacted]

[redacted]

Q. Were you in fact [redacted]

[redacted]

A. [redacted]

[redacted]

Q. Now, just to be sort of clear in our mind, [redacted]

[redacted]

[redacted] correct?

A. [redacted]

Q. [redacted]

[redacted]

[redacted]

A. [redacted]

MS. HELM: Object to the form.

Q. What's the name [redacted]?

A. [redacted]

Q. Right. So what was your [redacted]

[redacted]?

A. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Q. Again, you could [redacted]

[redacted]

A. [redacted]

MS. HELM: Object to the form.

A. [redacted]

Q. Due to the objection, let me just reask the question.

Could you describe for us what [redacted]

A. [redacted]

Q. All right. Were you able [redacted]

A. [redacted]

Q. All right. So what occurred after this or -- strike that.

[redacted]

[redacted]

[redacted]

MS. HELM: Object to the form.

Q. You can answer the question.

A. [redacted]

[redacted]

Q. Now, what was going on with [redacted]

[redacted]

[redacted]

A. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Q. All right. Would you state whether or not that [redacted]

MS. HELM: Object to the form.

Q. You can answer the question.

A. [redacted]

[redacted]

[redacted]

Q. Do you have an opinion as to whether at all times during [redacted]

Exhibit B-D

(Redacted and Filed Under Seal)

UNITED STATES DISTRICT COURT
DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC

- - -

Tuesday, June 20, 2017

- - -

** DO NOT DISCLOSE **

** SUBJECT TO FURTHER CONFIDENTIALITY REVIEW **

- - -

Videotaped deposition of RICHARD HARVEY, M.D., held at Mahaffey, Pickens & Tucker, 1550 North Brown Road, Suite 125, Lawrenceville, Georgia, commencing at 10:02 a.m., on the above date, before Susan D. Wasilewski, Registered Professional Reporter, Certified Realtime Reporter, Certified Realtime Captioner, Certified Manager of Reporting Services, Florida Professional Reporter, Certified Court Reporter (NJ), and Realtime Systems Administrator

- - -

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deps@golkow.com

Q. And what are they separated by?

A. [redacted]

Q. Okay. [redacted]

MS. HELM: Object to the form.

A. Well, as always, when we see -- the reason I remember this is because this is unusual, so, I mean, I really don't have to look at the notes too much to remember this, [redacted] Essentially, what we always do, [redacted]

Q. Okay. So let me break that down a little bit. [redacted] if you could explain to the

jury exactly anatomically [redacted]

MS. HELM: Object to the form.

A. We -- you know, [redacted] so -- but --

Q. Okay. And when you say -- [redacted] What did you mean by

that?

A. Well, [redacted]

[redacted]

MS. HELM: Object to the responsiveness.

Q. And, Doctor, is there a difference between [redacted]

A. Right. It's done -- [redacted]

[redacted]

Q. Based upon the [redacted]

[redacted]

Exhibit 4, [redacted]

[redacted]

A. [redacted]

Q. And again, just so I understand it, exactly [redacted]

A. [redacted]

Q. Was there -- would you state whether or not [redacted]

[redacted]

A. [redacted]

[redacted]

[redacted]

Q. All right. And would you state whether or not [redacted]

[redacted]

A. [redacted]

Q. Now, the records show as -- strike that.

[redacted]

MS. HELM: Object to the form.

A. [redacted]

Q. Okay. Let me just ask it this way. What is your understanding of [redacted]

A. [redacted]

Q. [redacted]

A. [redacted]

Q. Okay. [redacted]

[redacted]

MS. HELM: Object to the form.

A. My best recollection of that is that [redacted]

Q. Okay. Would you state whether or not [redacted]

MS. HELM: Object to the form.

A. Well, that is an old term that was used from -- there was a time when nobody got any kind of [redacted] That's no longer the case. [redacted]

[redacted]

Q. Okay. Now, [redacted]

[redacted]

A. [redacted]

Q. Okay. Now, [redacted]

[redacted]

A. [redacted]

[redacted]

Q. Okay. [redacted]

[redacted]

MS. HELM: Object to the form.

A. Correct. [redacted]

Q. All right. And you say you may or may not remember whether or not [redacted] --

MS. HELM: Object to the form.

Exhibit B-E

(Redacted and Filed Under Seal)

VERITEXT
LEGAL SOLUTIONS

Deposition of:

Sherr-Una Booker

February 20, 2017

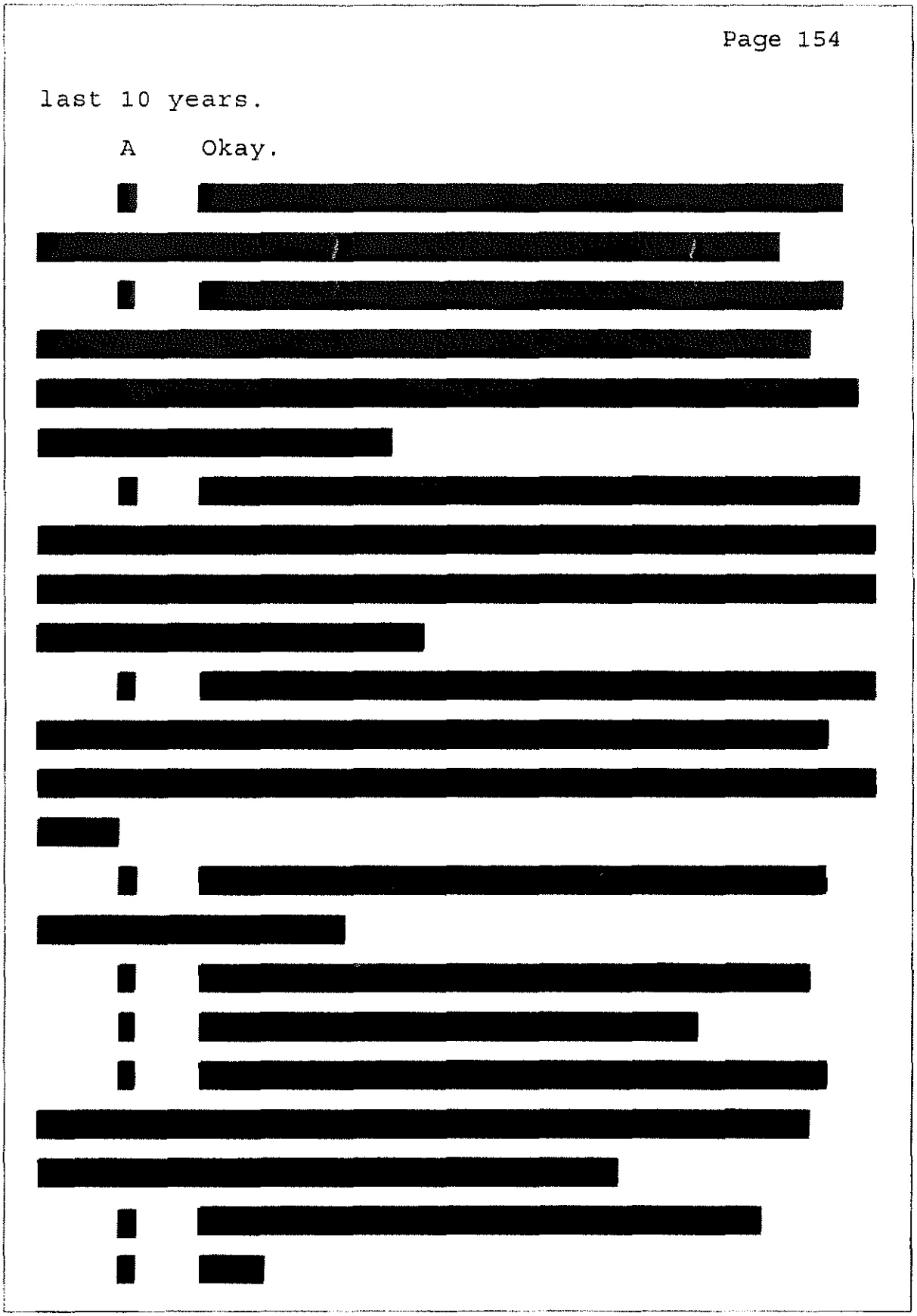
In the Matter of:

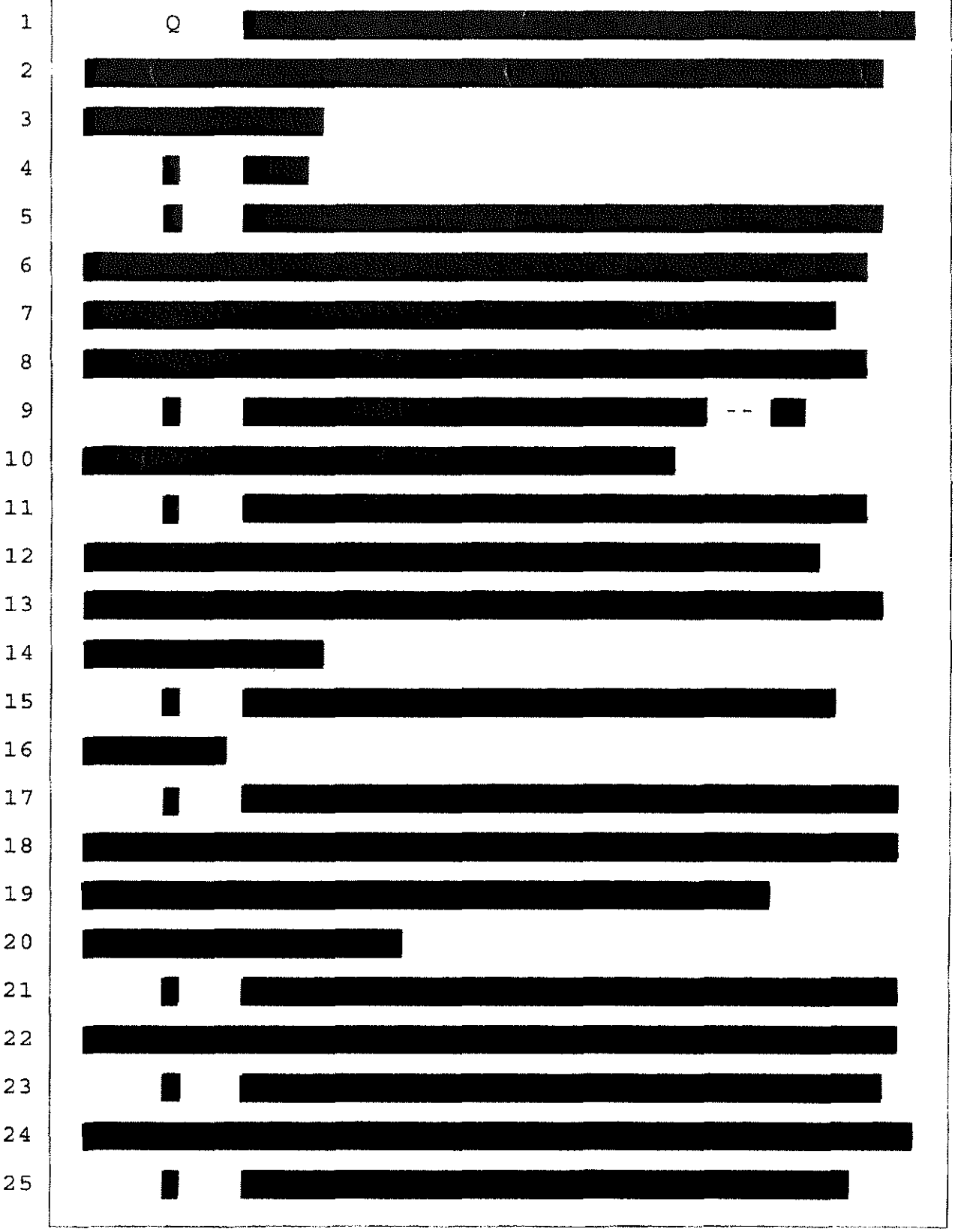
In Re: Bard IVC Filters Products Liability

Veritext Legal Solutions
1075 Peachtree St. NE , Suite 3625
Atlanta, GA, 30309
800.808.4958 | calendar-atl@veritext.com | 770.343.9696

last 10 years.

A Okay.

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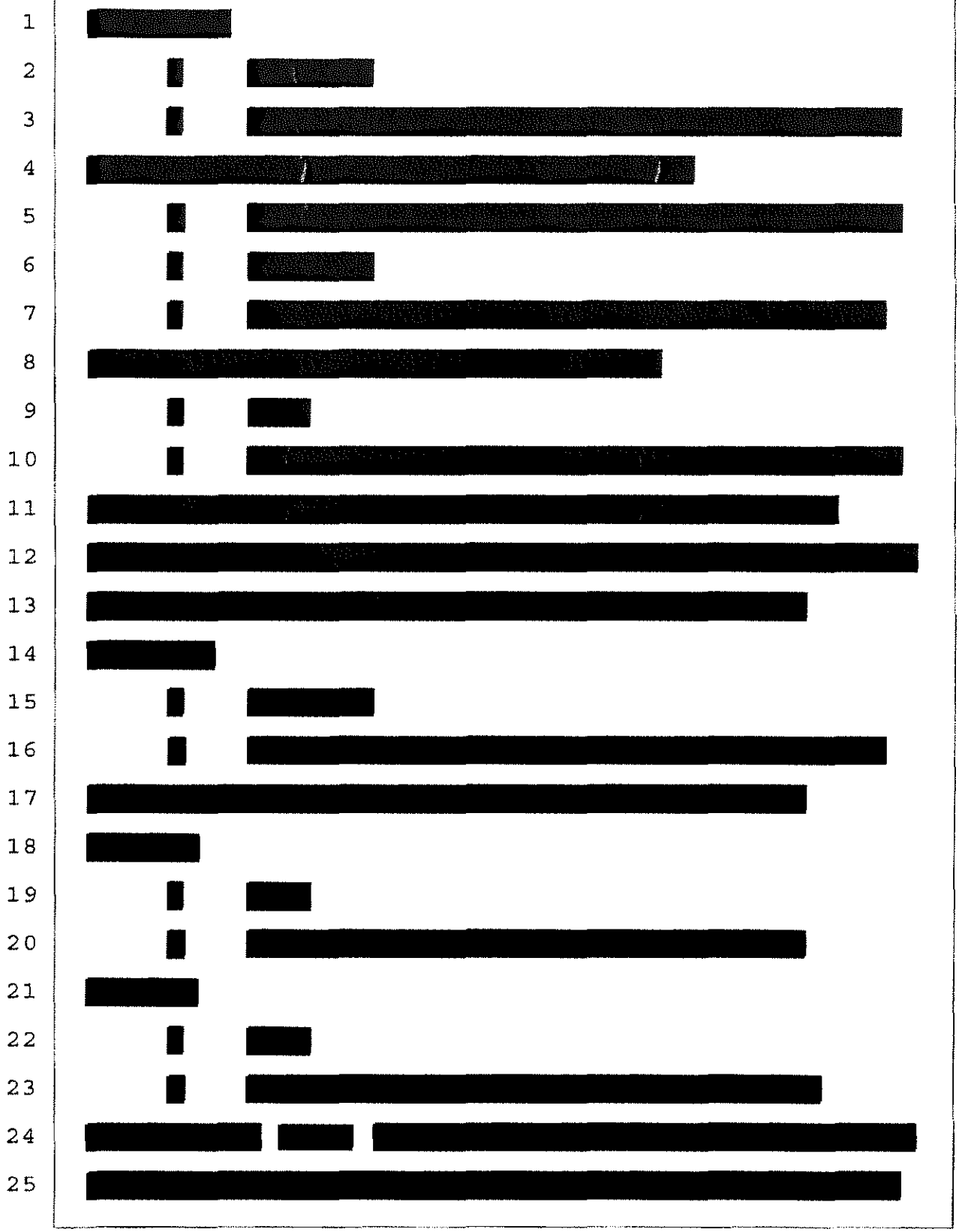

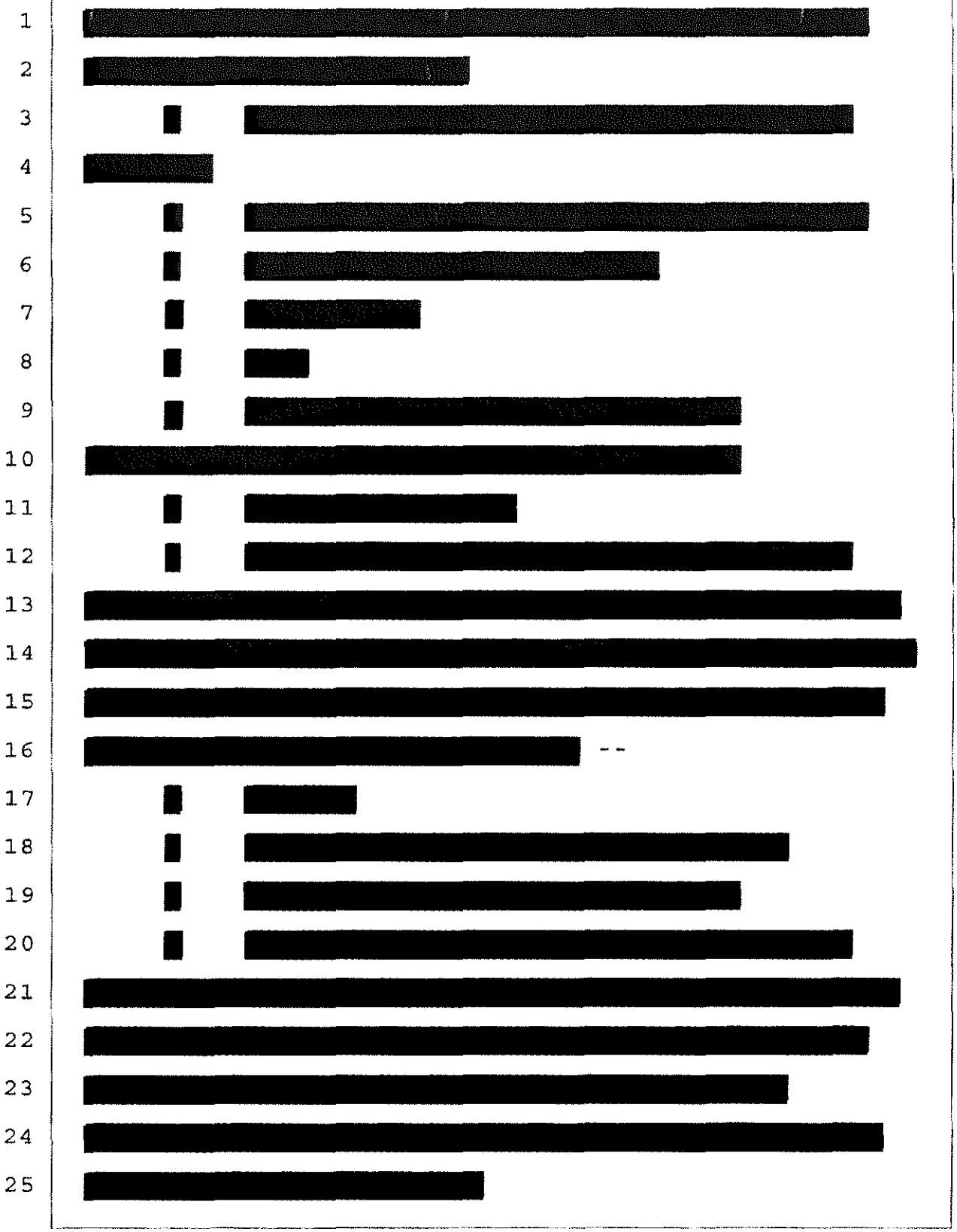

Exhibit B-F

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

- - -

In re Bard IVC Filters Products Liability Litigation

No. MD-15-02641-PHX-DGC

- - -

DO NOT DISCLOSE - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

- - -

April 7, 2017

- - -

Videotaped deposition of ROBERT FERRARA, held at Nixon Peabody, LLP, 50 Jericho Quadrangle, Jericho, New York, commencing at 8:39 a.m., on the above date, before Marie Foley, a Registered Merit Reporter, Certified Realtime Reporter and Notary Public.

- - -

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Deps@golkow.com

statement?

MS. KOWALZYK: Object to the form.

A. It's her opinion.

Q. But do you agree with it?

MS. KOWALZYK: Object to the form.

A. I -- I -- I don't know what that means by "trusted advisor" that she's referring it to, so I wouldn't necessarily agree or disagree.

Q. Did you consider yourself a trusted advisor to the physicians?

MS. KOWALZYK: Object to the form.

A. I considered myself a help in any way I could be.

Q. Can you keep reading the highlighted portion, please?

A. "The radiologists and support staff look to you for clinical knowledge."

Q. Do you agree with that statement?

A. At times, sure.

form; misstates prior testimony.

BY MS. LOURIE:

Q. You can answer.

A. I'm sorry, okay. One more time the question, please?

Q. Okay. Would you agree or disagree that the clinical knowledge that you would be giving your clients would be knowledge of a product's strengths and weaknesses?

A. Potentially.

Q. Would you agree that a primary concern of Bard in developing and selling medical products need to be the safety of the patient?

A. Sure, I think it's reasonable.

Q. And would you agree that doctors need to be able to trust you in giving them information that's reliable and trustworthy about the products?

A. I -- I believe that we have to give them accurate information.

Q. Do you believe that that information needs to be updated on a

the dissemination of it and tells you to give it out to the doctors, then you're okay with it?

A. If it's an approved item for distribution and they have directed us to distribute it, then yes.

Q. All right. But if you learn information that would potentially affect a doctor's decision about whether to implant a product and it's not on this approved dissemination list, do you feel a responsibility to tell the doctor that information?

A. Whatever -- whatever -- any information that's unapproved for me to disseminate to a physician I will not disseminate to a physician.

Q. So you're relying on Bard to give you the go-ahead on disseminating any information?

A. On -- on -- on approved information, yeah.

Q. All right. So if it wasn't approved by Bard, you weren't

disseminating it?

A. As far as I know.

Q. You didn't mean to anyway?

A. I don't think I did.

Q. Okay. Would you agree that doctors should use the safest product on the market that meets the needs of their patients?

MS. KOWALZYK: Object to the form.

A. I think that doctors should use whatever product they feel -- feel appropriate for their patients.

Q. And would a doctor be considering the safety of the product in making his determination of which product to use?

MS. KOWALZYK: Object to the form.

A. You have to ask the doctor.

Q. Okay. Well, you've been selling medical supplies for, what, 16 years?

A. Give or take. I think medical devices for a dozen or so, give or take.

Q. Okay. Would you agree that marketing materials put out by the manufacturer should be truthful and accurate and should present all pertinent information for the doctors to consider?

MS. KOWALZYK: Object to the form.

A. One more time.

Q. Do you agree or disagree that marketing materials put out by a manufacturer, in this situation Bard, I'll break it down, should be truthful?

A. Yes.

Q. Should the marketing materials put out by Bard be accurate?

A. Yes.

Q. Should the marketing materials put out by Bard contain all pertinent information for a doctor?

MS. KOWALZYK: Object to the form.

A. As defined by what Bard has approved and data for and can back up, claims that they can back up.

A. I think as a general assumption, physicians would expect that products are tested before they're released to the market.

Q. Would you agree or disagree that it is a good idea to hide data or studies from a doctor on a product?

MS. KOWALZYK: Object to the form.

A. I don't think that it is a good idea to -- to do that.

Q. Okay. Your background is in engineering, correct?

A. Mechanical engineering, correct.

Q. Have you ever done any sort of research on products yourself?

A. No, I have not.

Q. You've never been a part of the research or development program for Bard?

A. No. The -- the only input I've had is sometimes they'll ask the field their feelings about, let's say, angioplasty for example, because that's one I can remember, about what maybe

doesn't have a Bates number on it.

Do you know where you got this?

MS. LOURIE: All of these I can represent to you are documents that have been produced by Bard, that have been marked multiple times in depositions.

THE WITNESS: Can I write on this, or no?

MS. KOWALZYK: No.

THE WITNESS: Okay.

MS. LOURIE: I was trying to think if I have another copy.

THE WITNESS: It's not that important. I just like to make notes.

MS. LOURIE: All right.

BY MS. LOURIE:

Q. All right. I think we are up to Plaintiff's Exhibit Number 4, and I will ask you if you have ever seen that document before?

A. Not that I recall.

Q. All right. And I will tell you it is the results of the Asch study, as

you can see, and the Asch study, as you will see under the summary, or by looking at the entire document, had to do with the Recovery filter.

Do you see that?

A. Let me just -- give me one second to --

Q. Under the summary, if you'll look under the summary.

A. Okay. Hold on.

Q. Sure.

A. (Perusing document.)

So, if I'm reading this correctly, this says implanted the filter. It doesn't specify the filter that was implanted.

Q. If you look under "Summary" it says the Recovery filter.

A. Okay. The Recovery filter -- okay.

Q. All right. You feel comfortable talking about it, or do you need more time?

MS. KOWALZYK: Object to the

7.

Do you agree that that agenda item says that they're going to update the matrix comparing the migration rates of all known vena cavas?

A. Yes.

Q. If you look at number 8, do you agree that that agenda item stated that the team discussed a threshold level for migration and agreed that if a migration requiring surgical intervention is confirmed during the course of the investigation, that Recovery filters would be placed on hold pending the outcome of the investigation?

A. I agree that that's what number 8 says.

Q. Do you know if Recovery filters were ever placed on hold?

MS. KOWALZYK: Object to the form.

A. I don't recall offhand if they were placed on hold.

Q. Were you ever given any data or

information about the comparison of the migration rates of the known vena cava filters?

MS. KOWALZYK: Object to the form.

A. To my knowledge, I don't think there's any level 1 evidence that compares that. So I don't think we would have -- there's nothing that I can remember being given.

MS. LOURIE: Okay. I'm going to object to the responsiveness of the answer.

Q. The question was were you ever given any comparison data by Bard of the migration rates of all known vena cava filters?

MS. KOWALZYK: Object to the form; asked and answered.

Q. It's just a yes or a no.

Were you ever given that information?

A. I don't recall offhand.

(Exhibit Ferrara 6, memo from

MS. KOWALZYK: Okay.

(Exhibit Ferrara 7, e-mail from John Lehmann dated April 15, 2004, Bates No. BPV-17-01-00165419 through BPV-17-01-001654422, was marked for identification, as of this date.)

BY MS. LOURIE:

Q. Let me show you Plaintiff's Exhibit Number 7.

Have you ever seen that document before?

A. I don't believe so.

Q. What is the date of that document?

A. This e-mail is dated, what looks to be an e-mail is dated April 15th, 2004.

Q. What's the subject line of that e-mail?

A. "Crisis plan and supporting documents for your review."

Q. Were you aware when you came to work for Bard that there had been a crisis plan in place for the Recovery filter?

MS. KOWALZYK: Object to the

form.

A. I'm not aware of any crisis plan at Bard at all.

Q. No one shared the data contained in this plan with you?

A. As I'm not aware of the plan, I'm not aware of any data that would go with a plan.

(Pause.)

Q. Do you know John Lehmann?

A. I do not.

Q. Do you know Lee Lynch, Holly Glass, Donna Passero, you've already told us who Janet is, and Kellee Jones?

A. I don't know anybody other than Janet.

Q. Okay. All right. If you'll look in the middle of the page and read the --

A. Page 1?

Q. The first page. Where it says: "This is a simple story we should repeat again and again."

Will you read that next

Plaintiff's Exhibit Number 8.

And, do you know who Natalie Wong is?

A. I do not.

Q. If I tell you that she's an engineer at Bard, you can just assume that that's accurate, okay?

A. I -- I don't like to make assumptions.

Q. Okay. Well, I'm representing to you that Natalie Wong --

A. As fact.

Q. Yes, is an engineer or was an engineer at Bard.

A. Okay.

Q. Okay. Did anyone ever tell you that Ms. Wong had conducted a statistical analysis of data in May of 2004 with respect to the Recovery?

A. No.

Q. Did anyone at Bard tell you that she had compared the statistical data between Recovery and other filters on the marketplace?

BY MS. LOURIE:

Q. Have you ever seen a Health Hazard Evaluation from Bard?

A. I have no idea what that is.

Q. Okay.

A. So no.

Q. This one is dated December 17th, 2004. So that would have been the time when you were starting at Bard; is that right?

A. I may have just signed on at that point.

Q. That month though?

A. Yeah.

Q. Okay. So, this is report from David Ciavarella.

Do you know who he is?

A. I have no idea what that is.

Q. Okay. He's the medical director at Bard, or he was at that time.

In his summary, do you see at that point there were 76 reports of potentially serious hazards that had been reported? First line.

A. The first page, hold on.

(Perusing document.)

Q. Very first sentence.

A. Yep.

Q. Okay. And of those, 32 were judged to be serious and 10 reports were associated with patient death.

Do you see that?

A. Yes.

Q. Okay. Since you've never seen the Health Hazard Evaluation reports --

MS. LOURIE: Well, let me just strike that.

Q. Were you aware of these reported injuries?

A. No.

MS. KOWALZYK: Object to the form.

A. This -- this injuries, no.

Q. Were you aware that there had been 10 reported deaths?

A. No.

Q. If you will turn to page 5 of this document. Actually, page 4 of the

relevant or not, did you have the information?

A. If something is not statistically significant, I do not agree that it counts as data.

Q. Was it something that you were ever told, whether it was -- it's a simple question.

Were you told --

A. I don't feel it's a simple question. I think that it's the answer -- I'm answering the best way that I can, which is you're calling it data. For something to be data, it needs to be statistically significant.

Q. Okay. Let's just call it information.

Were you ever given any information about any differences between the Recovery fracture rates and any other IVC filter?

A. No.

MS. KOWALZYK: Object to the form.

A. "The G2 filter combines the best design features of Bard's existing vena cava filters to create a brand new permanent filter platform taking strength and stability to a new level."

Q. Did you have any understanding as to what in the G2 filter would make it have increased migration resistance?

A. I believe they may have changed something with the hooks on the feet, but I'm not a hundred percent sure.

Again, we're going back kind of a long time.

(Exhibit Ferrara 16, presentation titled G2 Filter - Summary of Features/Benefits, Bates No. BPV-17-01-00062014 through BPV-17-01-00062023, was marked for identification, as of this date.)

BY MS. LOURIE:

Q. The exhibit that you have in front of you is G2 Filter Summary of Features/Benefits. That might help you to answer some of the next few questions.

A. Okay.

Q. Have you ever seen the summary of features and benefits document?

A. Not that I recall. I don't know if they put it up at a sales meeting or something, but I don't remember offhand.

Q. We've already gone over this, but if you look at the second page which is Bates page 20, the first question at the top says: "Is the G2 filter retrievable?"

And what is the answer there?

A. "The G2 filter is not indicated for retrievable in the U.S."

Q. All right. And if you go back to the first page, which is -- ends in '2014, the increased migration resistance, would you agree that it was being marketed as being more resistant because it had wider leg span and stronger hooks?

A. Yeah.

Q. Okay. And was it being marketed as having reduced tilt?

A. Sure.

Q. Was it being marketed as increased fracture resistance, as having increased fracture resistance?

A. Sure.

Enhanced fracture resistance.

Q. Were you instructed to tell physicians about the way that these increased benefits were accomplished, or is that something that you didn't talk about?

A. I -- honestly, I don't remember offhand specifically.

Q. Were these factors, these benefits, something that you used as a selling tool?

A. The ben -- I mean, they potentially could have. I don't, at the time, remember specifically how we were, you know, selling the filter versus what the physician was currently using, offhand.

Q. Okay. Because at this time when the G2 filter came out, the Simon was still available?

this document?

MS. LOURIE: Yes.

BY MS. LOURIE:

Q. This new exhibit is another one of those Health Hazard Evaluations. This one's dated February 15th, 2006.

Since you testified already you've never saw any of these, I take it you've never seen this document.

A. Correct.

Q. All right. So, this one is in reference to the G2 and migration, and at this point in February of 2006, would you agree that there were 10 reports of migration, 9 of which were caudal, according to this report?

A. According to this summary, yes.

Q. Okay. And in the "Conclusion" section of this report, would you agree that Dr. Ciavarella concluded that the migration events with the G2 filter have been associated with a high percentage of caudal migrations accompanied by significant filter tilting and limb

pretty proud of yourself."

Q. Okay. So, Mr. Greer felt like the situation with respect to the filter problems was so terrible that it was held together with Scotch tape, smoke, mirrors, crying, et cetera, apparently, correct?

MS. KOWALZYK: Object to the form.

A. So, you would have to ask Jason how he felt about it.

Q. Okay. But you don't agree with Mr. Greer's assessment?

A. No, I don't agree with his assessment.

Q. All right.

THE WITNESS: Next document?

MS. LOURIE: Yep.

(Exhibit Ferrara 22, chart titled What is G2 trend relative to RNF?, was marked for identification, as of this date.)

BY MS. LOURIE:

Q. All right. Exhibit 22 is G2 trend relative to RNF.

RNF would be Recovery, correct?

A. Yes, I believe so.

MS. KOWALZYK: Do you have a copy for me?

MS. LOURIE: I'm sorry (handing.)

BY MS. LOURIE:

Q. Okay. If you look at this chart, will you agree, or can you tell the jury which product had more caudal migrations?

MS. KOWALZYK: Object to the form.

A. Caudal migration, according to this chart, it says G2.

Q. Okay. And that would be 14 percent compared to 3 percent; is that right?

A. On this chart, that's correct.

Q. Which one had more tilts?

A. On this chart?

Q. Yes.

A. This says 39 versus 16 with G2 having more.

Q. Which one had more perforations?

MS. KOWALZYK: Object to the form.

MS. LOURIE: What's your objection?

MS. KOWALZYK: This is a single page taken out of a 20-plus page presentation, and this completely mischaracterizes, used in this form, completely mischaracterizes what this data is summarizing.

MS. LOURIE: Okay. So you don't have an objection to the form of my question.

MS. KOWALZYK: I have -- I have objection to the foundation.

MS. LOURIE: Okay. All right. That's what I wanted to know, if you didn't like the way I was asking the question.

BY MS. LOURIE:

Q. Okay. Go ahead and answer the question.

A. Sorry, what was the question?

Q. Which product had more perforation?

A. On this chart, the number with G2 is higher.

Q. And what is the number for G2?

A. 36.

Q. And what's the number for Recovery?

A. Nine.

Q. Did anyone ever give you any of this information on this chart while you were working at Bard?

MS. KOWALZYK: Object to the form.

A. I don't remember ever seeing this chart, so no.

Q. Were you aware while you were working at Bard that the G2 had more caudal migrations than the Recovery?

MS. KOWALZYK: Object to the form.

A. I wasn't privy to the numbers for both of them. So I wouldn't be privy to any of that.

Q. So, the same would be true about the more tilting and more perforations?

A. Any tilting or any perforation rate I would not have specific access to.

Q. All right. So I would take it from this answer you would have not been able to relay that information to Dr. D'Ayala?

A. D'Ayala.

MS. KOWALZYK: Object to the form.

BY MS. LOURIE:

Q. I'm not going to get it right the entire time.

A. Okay. I could not have passed to Dr. D'Ayala any information that I didn't have or was approved to give him.

THE WITNESS: Moving on from this?

MS. LOURIE: Moving on.

BY MS. LOURIE:

Q. Have you ever heard of the migration push test?

A. No.

Q. -- on page 5.

A. Page 5. Page 5 for me says with the title "Product Development/Launch Schedule."

Q. Yes.

A. Okay.

Q. If you look at the second entry there, it's the G2 with caudal improvements.

So, at this point, which is February of '06, Bard is looking into a project to modify the G2 filter to minimize caudal migration.

A. Okay.

Q. According to the project status.

A. Project initiated to modify G2 filter to minimal caudal migration.

Q. They're trying to -- they're doing a failure investigation to determine the design and physiological root causes of the caudal migration?

A. Yeah, they're more R and D, it looks like.

Q. Okay. At this point, again I'll

ask you had anyone at Bard told you about this issue with caudal migration in the G2?

A. So, again I don't remember any specific time frames, and I wouldn't necessarily call it an issue. I had become aware that there were caudal migrations with G2 at some point, that there were reported cases.

Q. Okay. And did you ever talk to the doctors at New York Methodist about the issues with caudal migration?

MS. KOWALZYK: Object to the form.

A. I can't specifically --

Q. Or the fact that caudal migrations were being reported?

A. I don't specifically remember any conversations.

Q. All right. Flip over to page 8, and in this month there were four migrations reported for the G2; is that right?

A. Four, yes.

Q. Okay. Well, then I think that pretty much sums it up, that you were not interested in the Everest study or the push study or the comparative studies and you did not want any of that information to pass along to your physicians?

MS. KOWALZYK: Object to the form.

A. I would not agree with that.

The Everest study I do remember hearing something about. I don't recall the specifics.

Any of the internal studies that you're referencing that I'm unaware of were not my purview, and if they were relevant, I trust management and the internal in Bard to, at the time, give me that information once approved through their approval process to disseminate out to physicians. I at no point have an expectation to disseminate non-approved information to physicians.

Q. Okay. So you trusted Bard to pass along the information that was

important to pass along, and so did the physicians.

Would you agree with that?

MS. KOWALZYK: Object to the form.

A. I -- I would say that I trusted Bard to give to me the information that was appropriate and approved to give to me to pass along to physicians.

I feel that physicians have a reasonable expectation that a product is safe and effective and that if they have any questions, they can certainly ask the company for answers to them.

Q. Okay. You made quite a bit of money when you were working at Bard; is that true?

A. That's a --

MS. KOWALZYK: Object to the form.

A. That's a relative term.

Q. Okay, fair enough.

The year that you won one of those awards, I think I saw you got

Exhibit B-G

(Filed Under Seal)

Exhibit B-H

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION,) MD No.: 02641

IN THE CIRCUIT COURT OF THE SEVENTEENTH JUDICIAL CIRCUIT
IN AND FOR BROWARD COUNTY, FLORIDA

CLARE AUSTIN,

Plaintiff,

vs.) Case No.: 15-008373) Div.: 07

C.R. BARD, INC., a foreign corporation, and BARD PERIPHERAL VASCULAR, INC., an Arizona corporation; MATTHEW ROBBINS, M.D.; and CLEVELAND CLINIC FLORIDA,

Defendants.

DO NOT DISCLOSE - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

VIDEOTAPED DEPOSITION OF NATALIE WONG

Phoenix, Arizona
October 18, 2016
9:00 a.m.

REPORTED BY:
Robin L. B. Osterode, RPR, CSR
AZ Certified Reporter No. 50695

A. I was on new product development teams when I started back at Bard, and I was on PTFE grafts. And so if there was a failure mode, I would probably be working on root cause analysis.

Q. Fair to say it's something that you've done, at some level or another, since you started back at Bard in February 2004?

A. Yes.

Q. Is that something you know how to do?

A. Yes.

Q. Something you understand?

A. Yes.

Q. And why -- why does Bard do root cause analysis, I mean, what's their -- why do they do them?

A. To prevent failure modes from occurring.

Q. And is that something that's important to do?

A. Yes, absolutely.

Q. And why is it important?

A. Because we don't want complaints. We don't want patient injury.

Q. It's important to understand the root cause of failure modes to prevent injury to patients. Fair?

A. Yes.
Q. And safety of the patients is first and foremost for manufacturing companies. Right?
A. Yes.
Q. And -- and Bard feels that way?
A. Yes.
Q. So as of today, has Bard determined the root cause of filter fracture?
A. I don't know. I haven't been on filters the last several years.
Q. As of the time you left filters in -- in 2012, has Bard figured out the root cause of filter fracture?
A. No, not that I know of.
Q. How about filter migration?
A. No, not that I know of.
Q. How about perforations?
A. Not that I know of.
Q. How about tilt?
A. Not that I know of, no.
Q. Okay. And Bard continues to sell, and has all along continued to sell, the filter for placement in patients in a vein that leads directly to the heart and lungs. Right?
A. Can you repeat your question, I'm sorry?

THE WITNESS: I'm not sure what that means.
BY MR. DEGREEFF:
Q. You can answer.
MS. DALY: You can answer the question.
THE WITNESS: Okay, sorry.
Yeah, I think physicians should know, and I think we do communicate through the IFU.
BY MR. DEGREEFF:
Q. So you believe that in the IFU it states that Bard has failed to identify the root cause of the failure modes?
A. Sorry, no, not that part.
Q. Okay. As far as you know, has it ever been communicated to physicians that Bard has been unable to identify the root cause of the failure modes associated with its filters?
A. I don't know what's been communicated.
Q. As you sit here, are you aware of that occurring?
A. No.
Q. Is that something you personally would want your physician to know if you were going in and having an IVC filter placed?
MS. DALY: Object to the form.
THE WITNESS: I would want to know what

MS. DALY: He's talking about based on your data here.

THE WITNESS: That SNF -- sorry, SNF is better than G2 on caudal migration, yes.

BY MR. DEGREEFF:

Q. And it would be -- based on the data that's -- the available data that's in this spreadsheet, it would be inaccurate to say that the G2 was more stable than the -- than the RNF. Correct?

MS. DALY: Object to the form.

THE WITNESS: Yes.

BY MR. DEGREEFF:

Q. Let's see, look at the next page, if you would.

A. Sorry, what's the -- what's the first bullet point?

Q. It says "G2 Analysis." Right there.

A. Okay.

Q. And it says "How discovered?" Right?

A. Yes.

Q. And under -- underneath that it says, three of them say "Patient pain." Correct?

A. Yes.

Q. And so 3 of the 13, G2 caudal migrations

or analysis done within Bard which showed an association between caudal migration and tilt?

A. I think this is what -- what we were trying to do here was to understand how many caudals were associated with tilt, how many were associated with perforation and perforation/penetration.

Q. Was the ultimate conclusion of Bard that there was an association between caudal migration and tilt?

A. There was only eight datapoints here.

Q. I know I'm talking about ultimately. I mean, if this was something that was being analyzed, what was the ultimate conclusion? Was there an association between caudal migration and tilt?

A. I'd have to go back and look at the report.

Q. Is that something you don't know, as you sit here?

A. Yeah, I don't remember.

Q. Okay. Look at the next page, if you would. This is the caudal severity description. And I'm looking at type III and type IV. Caudal migration can be -- can result in a reintervention to remove the filter. Right?

A. Yes, for -- for the type III.

Q. And, yeah, and caudal migration can result

in the need to repair damage to a patient's anatomy?
A. Yes.
Q. And caudal migration can result in patient injury?
A. Yes.
Q. And caudal migration can result in a filter no longer providing its primary function of -- of protection from pulmonary embolism?
A. Yes.
Q. And if you're no longer providing protection of pulmonary embolism, is that a bad thing?
A. Yes.
Q. Why is it a bad thing?
A. Because you don't have protection from PE.
Q. And what happens if you don't have protection from PE?
MS. DALY: Object to the form.
THE WITNESS: You can have a really long clot to your heart.
BY MR. DEGREEFF:
Q. And can that ultimately result in death?
A. Yes.
Q. And pulmonary embolism can also -- I mean, excuse me, and caudal migration can also result in

excessive tilt; is that right?

A. Yes.

Q. And it can also result in an arm and leg -- an arm or leg in a side branch of the vena cava?

A. Yes.

Q. And caudal migration can also result in iliac or renal confluence?

A. I think here it's saying it could be in -- it could migrate to the iliac renal confluence.

Q. Yeah, you're right, correct. And caudal migration can also result in perforation?

A. Yes.

Q. And caudal migration can result in -- in death, correct, according to the type IV?

A. Yes.

Q. And life-threatening injury?

A. Yes.

Q. All right. Let's look at the -- there's a -- there's a -- a later one that says "G2 caudal threshold."

A. There's two of them, which one?

Q. The one -- the DFMEA.

A. The first one?

Q. Yeah.

A. Okay.

Exhibit B-I

(Filed Under Seal)

Exhibit B-J

(Filed Under Seal)

Exhibit B-K

MERIDIAN™ Filter System –Jugular/Subclavian Delivery Kit
510(k) Summary
21 CFR 807.92

AUG 2 4 2011

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a 510(k) summary upon which substantial equivalence determination is based is as follows:

Submitter Information:

Applicant: Bard Peripheral Vascular, Inc
1625 West 3rd Street
Tempe, Arizona 85281

Phone: 480-638-2906

Fax: 480-449-2546

Contact: Joni Creal, Regulatory Affairs Associate

Date: August 31, 2010

Subject Device Name:

Device Trade Name:	**MERIDIAN™ Filter System – Jugular/Subclavian Delivery Kit (MD800J)**
Common or Usual Name:	Filter, Intravascular, Cardiovascular
Classification:	Class II
Classification Panel:	Cardiovascular Devices
Product Code:	DTK
Predicate Devices:	ECLIPSE™ Filter System – Jugular/Subclavian Delivery Kit (K101431; Clearance June 25, 2010)

Summary of Change:

The primary modification to the predicate device, the ECLIPSE™ Filter System – Jugular/Subclavian Delivery System (K101431), compared to the subject device, the MERIDIAN™ Jugular/Subclavian Delivery System, is the addition of one downward pointing titanium anchor which is laser welded to each filter wire arm (6 total). In

addition, the Jugular delivery system has been modified to accommodate the filter design changes and minor changes have been made to the IFU.

Device Description:

The MERIDIAN™ Filter consists of twelve electropolished shape-memory nitinol wires emanating from a central electropolished nitinol filter hook. These 12 wires form two levels of embolic filtration: the six legs provide the lower level of filtration and the six arms provide the upper level of filtration. The legs contain hooks and the arms contain anchors to resist filter movement. The MERIDIAN™ Filter is intended to be used in the inferior vena cava with diameters less than or equal to 28 mm.

The subject MERIDIAN™ Filter System – Jugular/Subclavian Delivery Kit consists of a 10 French I.D. introducer sheath and dilator set and a delivery device preloaded with the MERIDIAN™ Filter. The introducer sheath and dilator are used to gain access to the inferior vena cava via a jugular approach using the Seldinger technique. The dilator accepts a 0.038" guidewire, enables a contrast medium power injection up to 800 psi maximum pressure, and is fitted with two radiopaque marker bands spaced 28 mm apart for caval sizing. The introducer sheath contains a radiopaque tip for identification of the distal end of the sheath and a hemostasis valve with a side port for injecting contrast medium via a syringe. The delivery device fits within the introducer sheath and delivery mechanism to deploy the MERIDIAN™ Filter.

Indications for Use of Device:

The subject device, the MERIDIAN™ Filter System – Jugular/Subclavian Delivery Kit, is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

MERIDIAN™ Filter may be removed according to the instructions supplied under the section labeled: Optional Procedure for Filter Removal.

Technological Comparison to Predicate Devices:

The technological characteristics of the subject device, the MERIDIAN™ Filter System – Jugular/Subclavian Delivery Kit, are substantially equivalent to those of the predicate device, the ECLIPSE™ Filter System –Jugular/Subclavian Delivery System (K101431), in terms of intended use, indications for use, application, user population, operating principle, delivery system design, filter bi-level design, fundamental scientific technology, packaging configuration, and sterilization method.

Performance Testing Summary:

To demonstrate substantial equivalence of the subject device to the predicate device, the technological characteristics and performance criteria were evaluated using *in vitro* and *in vivo* testing performed as outlined below:

In Vitro

- Fatigue Resistance
- Anchor Weld Tensile Strength
- Cephalad Migration Resistance
- Caudal Migration Resistance
- Removal Force
- MRI Compatibility
- Delivery System Trackability
- Delivery System Pushability
- Deployment Accuracy
- Filter Centering (Tilt)
- Arm/Leg Entanglement (Configuration)
- Biocompatibility
- Corrosion Resistance

In Vivo

- Retreivability
- Fatigue Resistance
- Cephalad Migration Resistance
- Caudal Migration Resistance
- Penetration Resistance
- Perforation
- Caval Patency
- Caval Damage
- Caval Narrowing
- Delivery System Trackability
- Delivery System Pushability
- Ease of Deployment (Deployment Force)
- Deployment Accuracy
- Filter Centering (Tilt)
- Arm/Leg Entanglement (Configuration)
- Filter Visibility Under Fluoroscopy
- Delivery System Visibility Under Fluoroscopy

The results from these tests demonstrate that the technological characteristics and performance criteria of the MERIDIAN™ Filter System – Jugular/Subclavian Delivery Kit is comparable to the predicate device and that the subject device can perform in a manner substantially equivalent to devices currently on the market for the same intended use.

Conclusions:

The MERIDIAN™ Filter System – Jugular/Subclavian Delivery Kit is substantially equivalent to the legally marketed predicate device, the ECLIPSE™ Filter System – Jugular/Subclavian Delivery System (K101431).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Bard Peripheral Vascular, Inc.
c/o Ms. Joni Creal
Regulatory Affairs Associate
1625 West Third Street
Tempe, AZ 85281

AUG 24 2011

Re: K102511
Trade Name: MERIDIAN Filter System – Jugular/Subclavian Delivery Kit
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular intravascular filter
Regulatory Class: Class II
Product Code: DTK
Dated: June 27, 2011
Received: June 28, 2011

Dear Ms. Creal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: MERIDIAN™ Filter System –Jugular/Subclavian Delivery Kits

Indications for Use:

The MERIDIAN™ Filter System –Jugular/Subclavian Delivery Kits are indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

MERIDIAN™ Filter may be removed according to the instructions supplied under the section labeled: Optional Procedure for Filter Removal.

Prescription Use_X_ AND/OR Over-The-Counter Use_____
(Part21 CFR 801 Subpart D) (21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102514

Exhibit B-L

(Filed Under Seal)

Exhibit B-M

(Filed Under Seal)

Exhibit B-N

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

- - -

IN RE: BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION	:	NO. MD-15-02641-PHX-DGC

- - -

July 18, 2017

- - -

DO NOT DISCLOSE - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

Videotaped deposition of MARK W. MORITZ, M.D., taken pursuant to notice, was held at the offices McCarter & English, LLP, 100 Mulberry Street, Newark, New Jersey, beginning at 9:07 a.m., on the above date, before Michelle L. Gray, a Registered Professional Reporter, Certified Shorthand Reporter, Certified Realtime Reporter, and Notary Public.

- - -

GOLKOW LITIGATION SERVICES
877.370.3377 ph | 917.591.5672 fax
deps@golkow.com

BY MR. DEGREEFF:

Q. And there are no high level studies that have been performed that show that filters are effective in saving lives, fair?

A. I don't know.

Q. You are not aware of such a study, are you?

A. I'm not.

Q. Are you aware of the recent study showing that filters don't increase the number of PEs that people -- that people have while filters are in place?

A. Say the question again.

Q. Are you aware of the recent studies determining that filters don't even increase the rate of PEs?

A. They don't increase the rate?

Q. Decrease. I'm sorry.

MR. BROWN: Object to the form.

THE WITNESS: I'm not aware of that study.

BY MR. DEGREEFF:

Q. You're not aware of that study?

A. No.

Q. Are you aware of any high level evidence establishing the effectiveness of filters in saving lives?

A. Other than -- other than these studies, I'm not.

Q. And nothing about those studies establishes that filters save lives, correct?

A. Yes, we agreed to that before.

Q. And, Doctor, you summarized several articles related to Bard IVC filters in your report, correct?

A. Yes.

Q. And consistently throughout those articles, they found a higher rate of fracture and migration with Bard filters over other filters, fair?

MR. BROWN: Object to the form.

THE WITNESS: I believe that's correct.

BY MR. DEGREEFF:

Q. Doctor, why do you think Bard didn't want to give you its internal documents?

MR. BROWN: Object to the form.

THE WITNESS: I don't know why they didn't give it to me, except it wouldn't have been relevant to what I was doing. It's probably a large number of documents, and I'm not sure that knowing who said what to whom and when they said it inside the company is relevant to what I'm doing.

BY MR. DEGREEFF:

Q. Why do you think Bard didn't give you the substance of their internal analysis of their failure rates, adverse event rates, versus other filters and versus permanent filters?

BY MR. O'CONNOR:

Q. But certainly for Bard filters?

A. For Bard filters.

Q. You saw what concerned you to be an increased rate of failures of Bard filters when you went to the literature and focused in on this case, a Bard case?

MR. BROWN: Object to the form.

THE WITNESS: Well, that's what the literature says, if you believe it.

BY MR. O'CONNOR:

Q. Well, and you being a doctor who has patients, and putting your patients' interests first and foremost, fair to say that you became concerned when you were preparing your opinions in this case about Bard filters?

A. Yes.

MR. BROWN: Object to the form.